

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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RAYMOND J. HORTON,

Plaintiff,

Docket No.: 12CV4436

- against -

GREENWICH HOSPITAL, YALE-NEW HAVEN
HOSPITAL and ST. JUDE MEDICAL S.C., INC.,

Defendants.
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**DEFENDANT’S
STATEMENT OF
UNDISPUTED FACTS
PURSUANT TO
LOCAL RULE 56.1**

Defendant GREENWICH HOSPITAL respectfully submit this statement pursuant to Rule 56.1 of the Local Civil Rules of the United States District Court of New York, and hereby sets forth the material facts to which there are genuine issues of facts to be tried. It must be noted by the Court that plaintiff has not submitted a separate Rule 56.1 statement and the responsive portion of this Statement is made in a good faith effort to comply with Local and Court rules should the Court consider plaintiff’s “Preliminary Statement and Statement of Facts”:

PLAINTIFF’S “STATEMENT OF FACTS”

1. During the procedure, and in a manner that is unknown to plaintiff and is not described in the GREENWICH HOSPITAL records, Dr. Setaro, and Greenwich’s physicians, inserted an Angio-Seal VIP device manufactured by St. Jude Medical, into the plaintiff’s groin area of his right upper thigh. See Pltf. Memo of Law at pg. 4.

Response: Plaintiff has made no efforts to depose Dr. Setaro or any of Greenwich Hospital’s staff in an effort to discover how the device was implanted. This issue is moot with plaintiff’s submission of Greenwich Hospital’s FDA MedWatch Report, as well as St. Jude Medical S.C., Inc.’s Investigation Letter and FDA Adverse Event Report, See Def Exh. “K.” The St. Jude Medical S.C., Inc.’s Investigation Letter and FDA Adverse Event Report were

not created by Greenwich Hospital Staff, are notarized, and do not meet the standards of the “Business Rule Exception” set forth by Fed R. Evid.803(5). As set forth in greater detail in Defendant’s Memorandum of Law in Opposition to Plaintiff’s Motion for Partial Summary Judgment, the St. Jude Medical S.C., Inc.’s Investigation Letter is hearsay and insufficient to defeat a motion for summary judgment. It is further uncontested that the Angio-seal device was created by St. Jude Medical, S.C., Inc. and they were in possession of the device before it was shipped to Greenwich Hospital.

2. “On January 13, 2013, plaintiff RAYMOND HORTON was re-admitted to the emergency room of defendant GREENWICH HOSPITAL due to a “pre-syncopal” episode while at home. The cause of plaintiff’s illness was not definitively identified, however, the physicians at GREENWICH HOSPITAL diagnosed, that it could have been caused by “an infection of the fragments of the Angio-Seal which remain in his femoral artery and surrounding muscle tissue,” to date. See Pltf. Memo of Law at pg. 6.

Response: As set forth in greater detail in Defendant’s Memorandum of Law in Opposition to Plaintiff’s Motion for Partial Summary Judgment against Greenwich Hospital only, a proponent of summary judgment must submit an expert affidavit in support of a claim that an act caused an injury. Defendant contends that plaintiff cannot link the purported injury of an infection above, without an expert affirmation. While plaintiff’s counsel’s “Notice of Motion for Partial Summary Judgment on the Issue of Liability” claims that the motion is supported by the Affidavit of Michael Attubato, M.D., no such affidavit is attached to said motion or referenced therein.

3. “GREENWICH and/or YALE-NEW HAVEN admittedly discarded the remaining portions of the fractured Angio-Seal Device placed in plaintiff.” See Pltf. Memo of Law at pg. 6.

Response: This argument is rendered moot by Greenwich Hospital’s disclosure of Greenwich Hospital’s FDA MedWatch Report, as well as St. Jude Medical S.C., Inc.’s Investigation Letter and FDA Adverse Event Report. See Def Exh. “I”. Only the MedWatch Report was generated by Greenwich Hospital, the Investigation Letter was drafted by Mike McCauley, Product Surveillance Analyst at St. Jude Medical, S.C., Inc. Id.

4. “Plaintiff’s amended complaint against GREENWICH HOSPITAL, dated March 27, 2013, alleges in paragraph “25”, under his “Third” claim, that the Angio-Seal VIP was “defective due to the negligent storage of the device by defendant GREENWICH HOSPITAL.” Plaintiff further alleges under his “Fourth” claim, in paragraph “35,” that “said product was defective in its manufacture, assembly, storage, and/or shipping when it was received by this defendant [GREENWICH HOSPITAL], and that “said product reached plaintiff in its defective condition.” Defendant GREENWICH HOSPITAL, denies each of those allegations in paragraphs “16” and “19” of its Amended Answer dated April 19, 2013, to the Amended Complaint.

Having thus admitted in its Amended Answer, that this device “was not defective” when it reached the plaintiff, defendant GREENWICH HOSPITAL, has eliminated the manufacturer ST. JUDE MEDICAL, S.C., INC., from this lawsuit. It has been further admitted in these pleadings that the device was in the sole possession and use of defendant GREENWICH HOSPITAL and its employees or agents, from the time it was received from ST. JUDE MEDICAL, until it exploded in plaintiff’s body. This is the very foundation of the legal

doctrine “res ipsa loquitor” upon which this instant motion is made. See Pltf. Memo of Law at pg. 7.

Response: As set forth in greater detail in Defendant’s Memorandum of Law, Greenwich Hospital answered by denying the allegation in so much as it pertained to them and otherwise denied knowledge or information sufficient to form a belief as to the allegation. See Pltf. Exhs. “C” and “D.” In no way can this be read as an “admission.” It is plain on its face that the Defendant was denying that the product reached plaintiff in its defective condition because of the Defendant’s actions, not that the device was not defective. Moreover, any ambiguity in the pleadings is due to the manner in which the complaint was drafted, which is why defendant denied the allegation.

5. “As a result of this occurrence, plaintiff has suffered severe and permanent personal injuries, pain, and virtual complete disability, which continues to date, and which will continue to worsen as plaintiff alleges.” See Pltf. Memo of Law at pg. 8.

Response: As set forth in greater detail in Defendant’s Memorandum of Law, a proponent of summary judgment must submit an expert affidavit in support of a claim that an act caused an injury. Defendant contends that plaintiff cannot link the purported injury of an infection above, without an expert affirmation. While plaintiff’s counsel’s “Notice of Motion for Partial Summary Judgment on the Issue of Liability” claims that the motion is supported by the Affidavit of Michael Attubato, M.D., no such affidavit is attached to said motion or referenced therein. This is further evidence why this motion is premature as Defendants have not had an opportunity to depose the Plaintiff or received any meaningful discovery from plaintiff. See Def Exhs. “E” and “F.”

PERTINENT PROCEDURAL BACKGROUND

1. In a complaint and amended complaint, plaintiff alleged that as a result of the actions of defendants Greenwich Hospital, Yale-New Haven Hospital, and St. Jude Medical S.C., INC., he suffered pain and suffering, permanent injury and disability due to defendants medical malpractice, negligence and wrongful acts and omissions in their medical treatment, use and manufacture of a vascular closure product and device known as the “Angio-Seal VIP”, as well as their requested and total failure to test, diagnose, locate, treat and remove portions of said product and device from plaintiff and their failure to obtain plaintiff’s informed consent to the use of such product and device and such medical procedures. Plaintiff further alleges that he suffered injury due to the use and manufacture, storage and/or shipping of a vascular closure device known as the Angio-Seal VIP, as well as their repeated and total failure to test, diagnose, locate treat and remove portions of said device. See Pltf’s Exhs. “A” and “C.”

2. Defendants served and filed answers to the complaint and amended complaint on behalf of Greenwich Hospital and Yale-New Haven Hospital on June 27, 2012 and April 29, 2013. See Pltf’s Exhs. “B” and “D.”

3. On September 19, 2012, counsel for Greenwich Hospital and Yale and for plaintiff attended a mediation session. See Def Exh. “B.”

4. On January 27, 2013, Defendant’s filed an initial Rule 26(a) disclosure. See Def Exh. “C.”

5. On February 4, 2013, a joint discovery order was entered into by all parties. Pursuant to the order, fact discovery was to be completed by July 1, 2013. See Def Exh. “D.”

6. On May 17, 2013, Defendants served plaintiff's counsel with an Amended First Set of Interrogatories. See Def Exh. "E." Plaintiff did not respond.

7. On June 18, 2013, Mr. Horton was notified by Defendants for his deposition. See Def Exh. "F." He did not appear.

8. On August 18, 2013, Defendants disclosed Greenwich Hospital's FDA MedWatch Report, as well as St. Jude Medical S.C., Inc.'s Investigation Letter and FDA Adverse Event Report. See Def Exh. "K." Only the MedWatch Report was generated by Greenwich Hospital, the Investigation Letter was drafted by Mike McCauley, Product Surveillance Analyst at St. Jude Medical, S.C., Inc. Id. The investigation letter is not notarized or sworn.

PERTINENT FACTUAL HISTORY

9. Mr. Horton, then seventy-one years-old, arrived at the emergency room at Greenwich Hospital on October 23, 2011, via Port Chester-Rye-Rye Brook EMS. See Pltf's Exhs. "E" at pg. 1-5. Emergency Medical Technician Michael Paniccia noted that Mr. Horton complained of a sudden onset of feeling like his heart was "beating out of his chest" and lightheadedness. Id. at 5. The Technician further noted that Mr. Horton was probably in ventricular tachycardia and 150 mg. of Amiodarone was administered via IV. Id. Subsequently, Mr. Horton reverted to normal sinus rhythm and reported feeling better.

10. In the Greenwich Hospital Emergency Department, Mr. Horton noted to be diaphoretic and tachycardic. See Pltf's Exhs. "E" at pg. 11 and 12. He described his chest pain as sudden onset with pressure and tightness, as well as sweating and shortness of breath. Id.

11. Mr. Horton's medical history as significant for coronary artery disease with stents placed in 1996, congestive heart failure, peripheral vascular disease, bypass surgery

in 2000, chronic Hepatitis C, and chronic obstructive pulmonary disease. See Def Exh. "A" at pg. 1.

12. On October 24, 2011, a cardiac catheterization was performed by John Setaro M.D. See Pltf's Exhs. "E" at pg. 76-81. During the procedure, a patent left anterior descending stent with non-critical re-stenosis was identified. Id. Upon completion of the catheterization, Dr. Setaro used an Angio-Seal device to close the puncture site, however, the Angio-Seal outer sheath then disintegrated into multiple pieces. Id.

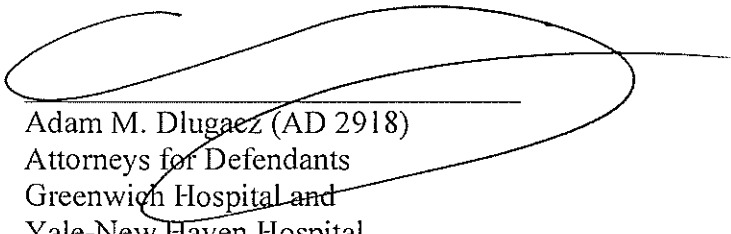
13. Mr. Horton was transferred to Yale on October 24, 2011 and would remain there until March 5, 2012. See Def Exh. "A" at pg. 2-4. At Yale, Mr. Horton underwent a further surgical procedure to remove the fragmented pieces of the product from his body. The surgeon made a medical decision not to remove the fragmented pieces. Id.

Dated: New York, New York
October 8, 2013

Respectfully submitted,

HEIDELL, PITTONI, MURPHY & BACH, LLP

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